K103207

MAY 20 2011

1 510(k) Summary

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Idaho Technology Inc. JBAIDS Q Fever Detection Kit

Introduction: According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitted by:

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Date Prepared: Oct. 29, 2010

Device Name:

Trade Name:

JBAIDS Q Fever Detection Kit

Common Name:

Real-time PCR amplification and detection system for targeted *Coxiella burnetii* DNA sequences

Classification Name:

Reagent Kit: Rickettsia serological reagents (CFR 866.3500)

Device Description:

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Q Fever Detection Kit is a fully integrated *in-vitro* diagnostic (IVD) system composed of the JBAIDS instrument with laptop computer, software, a freeze-dried reagent assay for the qualitative detection of pathogenic *Coxiella burnetii,* and 2 different sample preparation protocols for isolating target DNA from serum. Use of the JBAIDS DNA Extraction Control kit (not included) is also recommended.

The JBAIDS instrument, using Polymerase Chain Reaction (PCR) technology, is a portable thermocycler and real-time fluorimeter. The JBAIDS Q Fever Detection Kit is specially designed for PCR in glass capillaries using the JBAIDS instrument and hydrolysis probes for sequence-specific detection of the *C. burnetii* IS1111 DNA target.

The reagent kit contains 3 different types of freeze-dried reagent vials: Positive Controls, Negative Controls, and Unknowns (used for testing the patient sample). Each JBAIDS assay requires a Positive and Negative Control, and each sample is tested using an Unknown reagent vial which contains a multiplexed target and inhibition control (IC) assay.

Prior to testing, serum samples are purified using the Idaho Technology IT *1-2-3*™ QFLOW or IT *1-2-3*™ Platinum Path Sample Purification Kit. The resulting purified sample is added to an Unknown reagent vial, along with reconstitution buffer. A Positive Control and a Negative Control vial are prepared using reconstitution buffer and reagent grade water. Aliquots from each reagent vial are transferred to 2 reaction capillaries that are tested together in the JBAIDS instrument. The instrument is programmed to perform heating and cooling cycles that drive the PCR process. The heating and cooling cycles are generated using a heating coil and varying fan speeds. Fluorescence emission is monitored over 1 of 3 wavelengths, and the instrument software interprets the change in fluorescence to determine whether the target DNA is present.

When the organism is present, a fragment of *C. burnetii* DNA is amplified using specific primers. The amplicon is detected by fluorescence using a specific hydrolysis probe. The hydrolysis probe contains a short oligonucleotide that hybridizes to an internal sequence of the amplified fragment during the annealing phase of the PCR cycle. This probe has the 5' and 3' ends labeled with a reporter dye and a quenching dye, respectively. When the probe hybridizes to the specific DNA target, the Taq polymerase enzyme replicating the target-specific DNA hydrolyzes the probe, which separates the two fluorophores, thus allowing the reporter dye to fluoresce. Fluorescence is monitored at a wavelength of 530 nm. Inhibition is monitored using an internal inhibition control. The inhibition control consists of a linearized plasmid containing an artificial intervening sequence flanked by target assay primer sequences. Similar to the target, the IC probe also has the 5' and 3' ends labeled with a reported and quenching dye, respectively. Hydrolysis of the IC probe during amplification is monitored at a wavelength of 705 nm.

The level of fluorescence from each unknown sample and control is measured by the JBAIDS instrument. JBAIDS Software analyzes fluorescence amplification curves and reports results as Positive, Negative, Inhibited, or Uncertain. A failure of the Positive or Negative Control will result in the entire run being called Invalid. Failure of the Inhibition Control when no target amplification is observed yields an Inhibited result for the associated sample and requires retesting of that sample. A positive result for the target will override an inhibited result.

Intended Use: The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Q Fever Detection Kit is a qualitative real-time polymerase chain reaction (PCR) test kit intended to identify and detect target DNA sequence from Coxiella burnetii in serum collected from individuals suspected of having acute Q fever, typically 7-10 days after onset of symptoms or before antibody formation. This in vitro diagnostic (IVD) test is intended to aid in the diagnosis of Q fever in individuals presenting with signs and symptoms of acute Q fever when used in conjunction with other clinical and laboratory findings. This kit is only intended to aid in the diagnosis of Q fever of patients presenting in the acute stage of the disease. Negative results do not preclude *C. burnetii* infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

The JBAIDS Q Fever assay is run on the JBAIDS instrument using the Diagnostic Wizard. Results are for the presumptive identification of *C. burnetii* in conjunction with serology and/or other laboratory tests. The following considerations also apply:

- The diagnosis of acute Q fever must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence, in addition to the identification of *C. burnetii* from serum specimens.
- Sensitivity is decreased by ~25-40%, with no change in specificity, if the sample is collected after the patient has formed specific antibodies to C. burnetii, typically 7-10 days after onset of symptoms.
- The definitive identification of C. burnetii from serum specimens requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reports are required.

The test performance characteristics for this system were established with banked, frozen serum specimens that were sequentially received during a specified time period. The safety and effectiveness of other types of tests or sample types have not been established.

All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by JBAIDS instructors or designees prior to use. Use of this device is limited to designated Department of Defense (DoD) laboratories equipped with the JBAIDS instruments.

Substantial Equivalence: The JBAIDS Q Fever Detection System is substantially equivalent to other products in commercial distribution intended for similar use. The JBAIDS instrument has been previously cleared under K051713.

The predicate for the JBAIDS Q Fever Detection Kit is the Focus Diagnostics IgM and IgG IFA tests cleared under K922374 and K913906.
The following table compares the JBAIDS Q Fever Detection System with the predicate test.

Table 1. Similarities and Differences between the JBAIDS Q Fever Detection Kit and the Focus Diagnostics IFA tests

ELEMENT	JBAIDS Q Fever Detection Kit	Focus Diagnostics Q Fever IgG and IgM tests
Intended Use	Qualitative detection of *C. burnetii*	Detection and semi-quantitation of the human IgG and IgM antibody response to phase I and phase II *Coxiella burnetii* antigens and as an aid in the diagnosis of Q fever.
Indications for Use	Identification of *C. burnetii* in individuals suspected of having Acute Q Fever.	Serodiagnosis of both acute and chronic *C. burnetii* infections.
Technological Principles	Real-time PCR using hydrolysis probes.	Microscopic visualization of human antibodies for *C. burnetii* bacteria via a two stage "sandwich" procedure using a fluorescently labeled antibody that binds to the human antibodies.
Assay Target	IS1111 DNA sequences unique to *C. burnetii.*	Human antibody response to *C. burnetii.*
Specimen Types	Serum	Same
Instrumentation	JBAIDS instrument (K051713)	Fluorescent microscope
Time Required for Analysis of Specimen	Less than 3 hours	Same
Sample Preparation Method	Up front sample processing is required to extract nucleic acid.	Diluted samples are tested directly.
Sample Controls	Internal control is multi-plexed with the target test.	No sample specific control.
Testing strategy	One time point testing during the symptomatic phase of the disease.	Two serology time points are suggested. One during the symptomatic phase of the disease with follow-up testing 2-3 weeks later.
Optimal Window of Detection	Early in the disease course prior to antibody formation.	Later in the disease course due to the time required for antibody formation.
Test Interpretation	Automated test interpretation and report generation.	Subjective interpretation by user.
Physical Properties	Freeze dried reagents with reconstitution buffer and water provided in kit.	Liquid reagents. IgM and IgG are separate test kits.
Storage	Room temperature (18–28 °C).	Refrigerator temperature (2–8 °C)

The JBAIDS Q Fever Detection System is intended for the qualitative IVD detection of target DNA sequence from the *C. burnetii* pathogen. The system can be used to test human serum. The results from the PCR tests are used in conjunction with serology and

other laboratory tests and clinical information as an aid in the diagnosis of systemic Q Fever infection in individuals suspected of having the disease.

The predicate device and the JBAIDS system have a similar intended use; they both provide test results that aid in the diagnosis of Q Fever when considered with other clinical and laboratory evidence.

Performance Data

LoD

The JBAIDS Q Fever Detection System yielded positive results 20/20 (100%) with the JBAIDS Q Fever assay for serum samples spiked with the limit of detection level (10 $TCID_{50}$/mL) of live *C. burnetii* for both the IT 1-2-3™ Platinum Path and IT 1-2-3™ QFLOW^{dna} purification kits. In addition 10/10 (100%) of the isolates (see Table 2) included in the *C. burnetii* inclusivity panel were correctly identified by the JBAIDS assay the determined system LoD.

Table 2. *C. burnetii* Inclusivity Test Panel

Strain ID	Group
Nine Mile Phase I	I
QiYi	I
RSA334	I
Henzerling Phase I Salk	II
M44 – Grita	II
Idaho Q	III
Q173-P	IV
Q154-kAV	IV
WAV	V
Q229	V

Exclusivity

The analytic specificity evaluation of the JBAIDS Q Fever Detection System was conducted with organisms that are phylogenetically related to *C. burnetii*, as well as with unrelated organisms that are likely to be found in clinical samples.

The JBAIDS Q Fever Detection System assays also proved to be very specific.

- 22 of 22 non-*C. burnetii* strains (see Table 3) tested in the exclusivity panel were negative when tested at high concentration.
- 2 of 2 phylogenetically related genera, *Ehrlichia* and Neorickettsia, were evaluated *in silico*. This evaluation indicated that the primers and probes in the JBAIDS Q Fever assay would not cross-react with organisms from these genera.

Table 3. Exclusivity Panel

Organism	Relevance	Conc. Tested CFU/mL
Legionella pneumophila	Nearest Neighbor	10^6
Legionella longbeacheae	Nearest Neighbor	10^6
Legionella micdadei	Nearest Neighbor/Cross reactive with serology	10^6
Bartonella henselae	Cross reactive with serology	10^6
Rickettsia prowazekii	Other small obligate intracellular bacteria, agents of zoonoses	10^6
Mycobacterium tuberculosis	Similar symptoms	10^6
Brucella meliteusis	Similar symptoms	4.2×10^4
Orientia tsutsugamushi	Similar symptoms	10^6
Francisella tularensis	Similar symptoms	4.5×10^5
Salmonella enteric	Similar symptoms	10^6
Listeria monocytogenes	Similar symptoms	10^6
Haemophilus influenzae	Similar symptoms	10^6
Streptococcus pyogenes	Commonly encountered	10^6
Aggregatibacter actinomycetemcomitans	Commonly encountered	10^6
Haemophilus parainfluenzae	Commonly encountered	7.8×10^4
Acinetobacter baumannii	Commonly encountered	10^6
Vibrio cincinnatiensis	Commonly encountered	10^6
Escherichia coli	Commonly encountered	10^6
Staphylococcus aureus	Commonly encountered	10^6
Staphylococcus epidermidis	Commonly encountered	10^6
Pseudomonas aeruginosa	Commonly encountered	10^6
Serratia marcescens	Commonly encountered	10^6

Reproducibility

A multicenter reproducibility study was conducted in which a panel of specimens was tested twice a day for five days at two test sites and for seven days at a third test site. Results are summarized in Tables 4 and 5, and demonstrate the JBAIDS Q Fever Detection kit provides highly reproducible test results when testing at or above the established system LoD.

Table 4. Reproducibility Study Summary (Agreement with Expected Positive Results) for the JBAIDS Q Fever Detection Kit

Test Level	IT 1-2-3 Platinum Path Sample Purification Kit				IT 1-2-3 QFLOW^{dna} Sample Purification Kit				Both Purification Kits, All Sites	95% CI
	Site 1	Site 2	Site 3	All Sites	Site 1	Site 2	Site 3	All Sites		
5X LoD	21/21	15/15	15/15	51/51 100%	21/21	15/15	15/15	51/51 100%	102/102 100%	96.5-100.0
LoD	21/21	15/15	15/15	51/51 100%	21/21	15/15	15/15	51/51 100%	102/102 100%	96.5-100.0
LoD/15	11/21	8/15	13/15	32/51 63%	7/21	8/15	6/15	21/51 41%	53/102 52%	41.8-62.0
Detection ≥ LoD	42/42 100%	30/30 100%	30/30 100%	102/102 100%	42/42 100%	30/30 100%	30/30 100%	102/102 100%	204/204 100%	98.2-100.0
Detection all Levels	53/63 84%	38/45 84%	43/45 96%	134/153 88%	49/63 78%	38/45 84%	36/45 80%	123/153 80%	257/306 84%	79.4 -87.9

Table 5. Reproducibility Study Summary (Average Cp and %CV) for the JBAIDS Q Fever Detection Kit

Test Level	IT 1-2-3 Platinum Path Sample Purification Kit								IT 1-2-3 QFLOW^{dna} Sample Purification Kit							
	Test Location								Test Location							
	Site 1		Site 2		Site 3		All Sites		Site 1		Site 2		Site 3		All Sites	
	Ave. Cp	% CV	Ave. Cp	% CV	Ave. Cp	% CV	Ave. Cp	% CV	Ave. Cp	% CV	Ave. Cp	% CV	Ave. Cp	% CV	Ave. Cp	% CV
5X LoD	30.94	2.5	30.81	2.4	30.30	1.3	30.71	2.3	31.53	1.2	31.25	1.3	31.53	1.3	31.45	1.3
LoD	32.73	2.0	32.54	1.8	32.42	2.5	32.58	2.1	33.35	1.6	33.18	1.4	33.53	1.1	33.35	1.4
LoD/ 15	35.27	1.2	35.14	3.2	34.94	2.1	35.11	2.3	35.36	2.3	35.33	3.1	35.33	1.6	35.34	2.4

Note: Only the results for positive capillaries are included.

Clinical Studies

In addition to analytic studies, a multisite clinical trial was conducted.

The clinical performance of the JBAIDS Q Fever Detection Kit was performed using banked, frozen serum specimens that were sequentially received during a specified time period for which standard paired serological testing for Q fever had been previously performed. Three independent laboratories (located in distinct geographical regions; Australia, France and the Netherlands) were included in this

study. Serum specimens from a total of 749 subjects were evaluated in the study, however 284 were excluded (86 for inconclusive or incomplete serology, 21 due to environmental contamination, 7 for inconclusive JBAIDS results and all 170 samples tested at site 3 due to deviations from the study protocol). Table 6 provides a summary of demographic information for the 465 subjects included in this study.

Table 6. Demographic summary for JBAIDS Q Fever clinical study

Site		Site 1	Site 2
Number of Subjects		303	162
Sex	Female (%)	43%	31%
	Male (%)	57%	69%
Age	Mean	50	45
	Min	7	5
	Max	87	82
Specimen Collection Period		4/14/2008-10/15/2009	12/13/2005-6/26/2010

Prior to testing with the JBAIDS Q Fever Detection Kit, serum samples were purified using either the IT *1-2-3* Platinum Path or the IT *1-2-3* QFLOW^{dna} sample purification kit. Out of the 465 specimens, 183 specimens had adequate volume to be purified using both purification methods. This resulted in a total of 324 final test results for Platinum Path (170 from serology positive specimens and 154 from serology negative specimens) and 324 final test results for QFLOW (171 from serology positive specimens and 153 from serology negative specimen).

Of the 307 tests of serology negative samples, 222 had no antibody to *C. burnetti* and 85 failed to show a 4-fold rise in antibody titer between the paired acute and convalescence samples. All but one serology negative sample, (306/307, 99.7%) gave the expected negative result when tested with the JBAIDS Q Fever Detection Kit. The one false positive was obtained from one of the samples that failed to show a four-fold rise in antibody titer.

Of the 252 tests on samples that were serology positive based upon a four-fold rise in antibodies, the JBAIDS Q Fever Detection system correctly identified the presence of *C. burnetii* in 17.8% (45/252) samples. However, the positive JBAIDS test result rate for those samples which exhibited seroconversion was significantly higher at 62.9% (56/89). These data are consistent with several published reports indicating that PCR detection of *C. burnetii* declines significantly once specific antibodies are detected by serology.

Clinical sensitivity ranged from 29-81% (variation between sites) on specimens collected prior to seroconversion. As shown in Table 7, the clinical sensitivity for the JBAIDS Q Fever Detection Kit was different at the two study sites. Site 1 had a

lower detection rate (29% for specimens purified using the QFLOW^{dna} extraction kit and 47% for specimens purified using the Platinum Path purification kit) when compared to the detection rate at site 2 (81% for specimens purified using the QFLOW^{dna} extraction kit and 77% for specimens purified using the Platinum Path purification kit). The differences observed at the two study sites may be the result of differences in organism strains, patient population or patient management. The clinical specificity was 100% at both sites for serology negative samples that had no antibody to *C. burnetii*.

Table 7. Sensitivity and Specificity for the JBAIDS Q Fever Detection Kit in Samples Tested for Acute Q Fever that were Seronegative

SERONEGATIVE SPECIMENS					
		Sensitivity		Specificity	
Site	Purification Kit	TP/ (TP + FN)	Percent	TN/ (TN + FP)	Percent
1	Platinum Path	9/19	47% (95% CI=24-71%)	40/40	100% (95% CI=91-100%)
	QFLOW^{dna}	5/17	29% (95% CI=10-56%)	39/39	100% (95% CI=91-100%)
2	Platinum Path	20/26	77% (95% CI=56-91%)	71/71	100% (95% CI=95-100%)
	QFLOW^{dna}	22/27	81% (95% CI=62-94%)	72/72	100% (95% CI=95-100%)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Idaho Technology, Inc.
c/o Beth Lingenfelter
Director of Regulated Products
390 Wakara Way
Salt Lake City, Utah 84108

MAY 20 2011

Re: K103207
Trade/Device Name: JBAIDS Q Fever Detection Kit
Regulation Number: 21 CFR 866.3500
Regulation Name: Rickettsia serological reagents
Regulatory Class: Class I
Product Code: OVF
Dated: May 17, 2011
Received: May 18, 2011

Dear Ms. Lingenfelter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K103207
Device Name: JBAIDS Q Fever Detection Kit

The Joint Biological Agent Identification and Diagnostic System (JBAIDS) Q Fever Detection Kit is a qualitative real-time polymerase chain reaction (PCR) test kit intended to identify and detect target DNA sequence from *Coxiella burnetii* in serum collected from individuals suspected of having acute Q fever, typically 7-10 days after onset of symptoms or before antibody formation. This *in vitro* diagnostic (IVD) test is intended to aid in the diagnosis of Q fever in individuals presenting with signs and symptoms of acute Q fever when used in conjunction with other clinical and laboratory findings. This kit is only intended to aid in the diagnosis of Q fever of patients presenting in the acute stage of the disease. Negative results do not preclude *C. burnetii* infection and should not be used as the sole basis for diagnosis, treatment or other management decisions.

The JBAIDS Q Fever assay is run on the JBAIDS instrument using the Diagnostic Wizard. Results are for the presumptive identification of *C. burnetii* in conjunction with serology and/or other laboratory tests. The following considerations also apply:

- The diagnosis of acute Q fever must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence, in addition to the identification of *C. burnetii* from serum specimens.
- Sensitivity is decreased by ~25-40%, with no change in specificity, if the sample is collected after the patient has formed specific antibodies to *C. burnetii,* typically 7-10 days after onset of symptoms.
- The definitive identification of *C. burnetii* from serum specimens requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reports are required.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K103207

Indications for Use Form

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie L. Poole

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K103207